TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
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STAKEHOLDERS MEETING WITH)
MONSANTO)
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UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
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STAKEHOLDERS MEETING)
WITH MONSANTO)
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Training Room 1
4700 River Road
Riverdale, MD

Friday
February 27, 2004

The parties met, pursuant to the notice, at 12:02 p.m.

BEFORE: MS. CINDY SMITH
Deputy Administrator

APPEARANCES:

For the U.S. DEPARTMENT OF AGRICULTURE:

REBECCA BECH, Assistant Deputy Administrator
JOHN TURNER
NEIL HOFFMAN
MICHAEL WACH
SUSAN KOEHLER

Meeting with: Monsanto
RUSSELL SCHNEIDER, Director
ROY FUCHS, Ph.D., Lead, North America Biotechnology Regulatory
RAYMOND C. DOBERT, Ph.D., Regulatory Affairs Manager Oilseeds
SHEILA A. SCHUETTE, Ph.D., Director, Regulatory Affairs

PARTICIPANTS:

LEVIS HANDLEY
ROBYN ROSE
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CRAIG ROSELAND
MEGHAN THOMAS
HALLIE PICKHARD
JIM WHITE
LAURA BARTLEY

P R O C E E D I N G S

(12:02 p.m.)

MS. SMITH: Good afternoon.

UNISON: Good afternoon.

MS. SMITH: Welcome to our Stakeholders Discussion Series on our upcoming EIS and revised plant biotech regulation. I apologize to you, Russ, for listening to this background twice.

MR. SCHNEIDER: Thank you.

MS. SMITH: But I think it is useful for everyone coming in to know what the problem is.

We thank you for taking time from your busy schedules to be here with us today and we are really appreciative of the input that I am sure you will be sharing with us.

The purpose of these briefings is two fold: First to give us an opportunity to share information about our plans to look forward to completing the environmental-impact statement on the EIS, as well as to revise our Plant Biotech Regulations. The second purpose of the meetings is to gather diverse and informative input, which will support the decision making on our part in developing our new regulations.

We have here from BRS most of our management team, as well as several members of our staff; and,

when available, other key APHIS involved in supporting BRS on this effort. I should also mention two key individuals who have now been dedicated to providing full-time management of our work to complete both the EIS and the revised regulations.

The first is Dr. John Turner, who I am sure you are familiar with. John is a very important member of our leadership team, as you are aware. I am very pleased to say that John is leading our effort on a full-time basis for this project. And the second individual with whom you may not be familiar is Dr. Michael Wach. Michael is a recent BHS hire as an environment protection specialist within our environmental analysis unit. In addition to possessing a Ph.D. in environmental law and a J.D., Michael brings research experience in plant pathology and weed science, as well as legal experience working on cases involving both the Clean Water Act, the Clean Air Act, NEPA, and other environmental laws.

With that, I will turn it over to John, who will provide some additional information and then we will be able to open it up for either your sharing of a statement or an interactive discussion with us.

MR. TURNER: As I think you all know, we have been in discussion with our sister agencies: the

EPA and the FDA, and also with the White House on revisiting the coordinated framework and any changes that might need to be made. We have, of course, included that the coordinated framework as it stands, has provided an appropriate and science-based regulatory approach for biotechnology.

But, still, the Plant Protection Act of 2000 provides an unique opportunity for us to revise our regulations and possibly to expand our authority while still leveraging the experience we gained in regulation over the years. Our revisions that we are considering would position us well for future advancements.

We concluded the discussions with some overall agreement on how the biotech-regulatory approach would evolve. But still, as I said, this early in the process where there is much opportunity for public and stakeholder input has been moved forward. So, given this, what we would like to do with these meetings and what they are for is for us to hear from you, to hear your thoughts; and also to have an informal give and take of ideas.

It is an unique opportunity for us to be able to have these because we have not yet begun the formal rule-making process. So we are free to speak

openly and to share with you the stakeholders' and public's thoughts.

You will notice that these discussions are being professionally transcribed. This is for two reasons: First, we want an accurate record of our discussions to facilitate our ability to capture and to refer to your input in the future. And secondly, in the interest of transparency and fairness to all the stakeholders, we will be making available, as part of the public record and possibly on our Web site, all the stakeholder discussions, so that the public and each of the stakeholders have the benefit of all the discussions that we are conducting this week.

I want to emphasize that while we are happy to share the thoughts and information that we have at the present moment, and our direction and in our thinking at BRS, it is an evolving process. So your input, public-and-stakeholder input, will influence our thinking. In addition, those within USDA, including our administrator, the undersecretary and the Office of General Counsel; and, of course, the secretary will also provide insights and direction as well.

While we value all input as important to realize that it is an evolving discussion, we might

have some enthusiastic discussion today over some aspect, but it is subject to change and evolution as we gain more input.

Finally, on that note, it is very difficult to say exactly what the final provisions will look like. But what we can share are our overall priority areas and areas of emphasis because these will guide us in the process. The first of those is rigorous regulation, which thoroughly and appropriately evaluate -- since your safety is supported strong compliance and enforcement.

The second is transparency of the regulatory process for decision making to stakeholders and the public. This is crucial for public confidence. And, of course, we want a scientific-based system insuring that the best science is used to support regulatory decision making to insure safety. Communication, coordination and collaboration with a full range of stakeholders is also a major area of emphasis.

And finally, I would mention: international leadership. We want to insure that international biotech standards are science based as are ours. We want to support international capacity building; and we need to consider the international implications of policy and regulatory decisions.

As we prepare to being our discussions, I would let everyone know that for effective transcription, all questions need to be directed into a mike. Then, you are fine as long as there is one on your table, you don't have to bend over to speak directly into it. But for the sake of the transcriber, the very first time that you speak,if you could state your name after that, I don't think that will be an issue.

With that, I will turn it over to you to hear your comments and discussion.

MR. FUCHS: Thank you. I am Roy Fuchs from Monsanto. I am the lead for the biotech regulatory for North America. I would just to start off with some general introductory remarks.

First, on behalf of Monsanto, we appreciate the opportunity to be here today and your willingness to meet with us. One of our intents today is to better understanding and have better clarity around some of the questions, so that as we come back with our detailed comments that they can be as valuable and protective as they can be.

I would also like to acknowledge USDA and really your sister agencies as well for the work that you have done over the last several decades. It is

clear from the hundreds of millions of acres of biotech products that have been planted to date with no adverse effects confirmed from either the environment or the food or the feed that the science-based regulations that you have developed with the first generation of products have been effective and have, I think, secured the safety as a priority for all of us.

We do also support, as you are going through this process -- that is, we look at the products that are in the pipeline and the second and third generation of products, that it is appropriate and very timely that you do look at the regulations for modifications based on a very extensive database in terms of familiarity both in terms of commercial products as well as your extensive experience on field testing with literally tens of thousands of field tests that have been conducted to date.

We also recognize that you totally support the science basis of the regulations, as we look forward with the types of products that will be coming forward from ourselves and the broad scientific community. Of course, focusing those on potential risks that we all are familiar with as well as the familiarity and experience that have been developed to

date. Which really leads me to the first question that I would like to raise and that is that you have in your questions in several areas refer to risk base and categories of risk.

As we look at many of the questions that you have raised,many of those have running through them a commonality that are based and should be based on relative risk, whether we are talking about field testing, commercialization, how the USDA plans to handle imported products or adventitious presence, or even the shipping requirements? These really all have a common thread of looking at relative potential-risk categories.

So one of the first questions that I have is: How you have looked at these categories and whether you see a plan to use that as a commonality across the various categories of regulations and modifications in regulations that you are considering? So we think that it is a very firm basis of all five areas I have mentioned that your direction will probably be based on these risk categories.

So anything more that you can share with us about the types of categories, the criteria for these categories, would be really very helpful for us in finalizing our own comments.

MS. SMITH: I think I can start with that and John can add to it. That is a correct observation. Our intention is to base our revised regulations on U.S. science. As you look at what we have identified there under No. 2, where we are talking about establishing risk-based categories. What we tried to do is give some examples of things that would fall into those categories.

One observation that I am sure you have made is that there are some things listed there that have different levels of risk within the same category. So the clarification that we should make up front is it our intention to establish risk-based categories. But, at this point, that risk was -- it is very early in the process and we are very open as to how best establish what those different levels of risk should be and then good examples of what would fit into those categories.

So those would be the kinds of comments that we would be seeking, so that could note to you while we gave the pharmaceutical and industrial crops as an example of the highest level of risk, it is worth noting that there are members of that group that clearly do not pose the same level of risk as other members. We gave that kind of as an example of the

kind of thing that we could consider at a higher risk. But that does not mean that something couldn't be looked at within that group; and then after evaluation, be shown to have less risk, so then it goes into a lower-risk category.

But the kind of specific comments that we are looking for in your written comments are: What kinds of criteria we should use to determine the different levels of risk?

MR. FUCHS: One follow-up question may be more specifically is in some of the background and what you have done previously. You look at risk, which is very appropriate on the crop, the trait and the environment. And I take it that you are looking again for a criteria within each of those kinds of categories; and that the same trait in different crops would pose different risks. So those are the types of categories you are requesting specific information?

MR. TURNER: Yes.

MR. FUCHS: But with that as a kind of starting point. The topic that we have had in numerous discussions on with an industry and I know that the USDA has considered with your sister agencies over the last several years is around adventitious presence.

Given the importance and the U.S. being a leader in biotechnology, of course, this is a nationally -- and when we look at international trade and the international regulations, we understand from your comments that the USDA will be issuing guidance relative to that and relative to adventitious presence. However, we were interested as you have taken actions in the last years with some of the other categories like PMPs and PMIPs prior to finalizing your new regulations. Are you considering issuing guidance for adventitious presence prior to finalizing the final new regulations, or are you doing that within the context of the new regulations, which I assume will take considerable time before those are finalized and issued?

So from a time perspective, I think it is a very important and quite urgent issue for both USDA and your sister agencies to address. I am just curious as to the time frame that you were looking to issue guidance?

MS. SMITH: We do recognize the urgency for this issue. We will certainly address adventitious presence within the text of the new regulations. We see that the fuller authorities in the Plant Protection Act put us in a very good position when we

address adventitious presence.

That said, we also may optionally issue some guidance before such time as our regulations are concluded. As we continue to do our work on adventitious presence, we see that there is something that we can go ahead and issue prior to the regulations.

MR. FUCHS: And maybe one follow up to that. Again, I know when you are in intra-agency discussions, you have discussions with, again the FDA and EPA. Can you give us any better understanding of the guidance that you will provide? I take it that it will be in coordination with the other agencies.

Do you have any comment on how that coordination will occur that you could provide to us?

MS. SMITH: With respect to AP you mean?

MR. FUCHS: Yes, with adventitious presence.

MS. SMITH: What we are talking about there is moving to a multi-tiered, risk-based permitting system. So, within that permitting system, we may see a level of risk, or a level of permits that doesn't have risk associated with it, or significant risk associated with it.

So what we could look at is establishing criteria that we would establish jointly with FDA and

EPA. So, if there was some low, intermittent level of an occurrence of something that had not fully cleared the regulatory system, yet they could meet those safety criteria that would be jointly developed for them in the EPA, then a decision could be made about whether that is, in fact, a violation of our regulatory -- it would be something that would be, except for being a violation of our rights.

John, if you want to add to that.

MR. TURNER: Yes. Your first question was about the risk categories and how they related to some of these other things, and certainly that is part of the thinking that they may. So there may be one category for which there is allowable AP. As Cindy said, then the criteria for that category would be established on an intra-agency basis.

As you also note, I am sure from the August 2002 notice, the FDA has said that they will do early safety reviews, So that is something that we could consider in our categorization scheme. It is one of the things that we are considering is to use that specific categories that might relate to whether AP was allowable.

MR. DOBERT: This is Ray Dobert with Monsanto. I would just like to ask a follow-up on

that. What would you foresee as a potential mechanism by which you would be able to get that more informal feedback from either the EPA or FDA? o you think that that is just more like a memorandum of understanding or would it have to be something more formal that either of the agencies would need to undertake in order to provide APHIS with the kind of feedback that you would be looking for?

MS. SMITH: I would think that NMOU is one likely possibility.

MR. SCHNEIDER: I am Russ Schneider with Monsanto here in Washington, D.C. As we have discussed a number of times, I think we all know that we in fact supported the field-trial system with a level of review and oversight that is really commensurate with the crop traits and the potential risks.

Does APHIS foresee the continuation of this system of expedited reviews for familiar crop that present low risks? And if so, and if not, does it change -- for field trials will APHIS provide advance notice of those changes in order not to impact our field trials?

MR. TURNER: By expedited review, you are not talking about extensions of petitions. You are

talking about a notification versus a permitting kind of system?

MR. SCHNEIDER: Right.

MR. TURNER: With the different categories, one of the things that is going to happen is, if we go this route of eliminating notifications, so that would become a certain class of permit, possibly that would be the attributes of that.

So exactly the time periods were not to that level of detail, but that concern certainly will be noted and I think that we can address that.

MR. SCHNEIDER: But there would be time allowed and given enough warning that something would change that we wouldn't even have gotten into our program? Okay.

MS. SMITH: I think that certainly, at the point that it was reissued, our proposed rule that wouldn't be effective immediately that would give some sense of the direction and again one of the things that we are cognizant of is: What kind of transition is going to have to be to the new requirements?

So we wouldn't be keeping that forward.

MR. SCHNEIDER: Okay.

MS. SCHUETTE: Keeping that in mind. And the time of year is very important for troubleshooting

at Monsanto.

MS. SMITH: Right.

MR. FUCHS: The other question and you kind of addressed it earlier, John, relative to the risk categories: As you are well aware, we do a lot of field testing; and when we are developing new products, it has become more and more critical that a lot of our decision making about the efficacy of traits now requires field testing with things like insect protection and herbicide tolerance.

We could get much better data in a greenhouse. When we are thinking about other traits, like nutritionally enhanced traits, that yield a lot of the quality applications, we become more and more dependent on field testing as a scientific community to evaluate the efficacy of the products we are testing.

So, for us, having flexibility and looking again in the risk categories of crops and whether we are talking about genes that are back in the same crops, or crops with a familiarity of history, like corn and soy bean. You know how you look at regulations, then field testing on those becomes really critical. I am sure that you heard a lot from the scientific community, as well as ourselves, that

field testing is just a necessary part of an evaluation process that has become more and more critical.

So it is a very important part for ourselves and for our own product development in that it maintains flexibility to use those small-scale field testing and large-scale and large numbers of genes to be able to augment; and, as a feedback cycle, actually make very basic decisions relative to research and development.

MR. TURNER: That was important. Does anybody else want to comment?

MR. FUCHS: Relative to that end, Russ's question, we certainly acknowledge and the National Academy acknowledges that notification is something that works if you want to retain all of the aspects of it. They are all APHIS authorizations and we want to connote that there is oversight over these, which there is and there always has been.

And maybe that final comment that we would just like to make on behalf of field testing and some people use a distinction in terms of risk relative to whether it is a known or an unknown trait. It is interesting as you think about the source of the trait, and we do a lot of research internally into

geomics, in putting the card and genes back in the card, some of which we may know and some of which we may not know.

As you always have done, the source of those genes, whether or not we know the function, knowing where they came from, the safety of the organism that they were derived from becomes very important. We and others look at putting a large number of genes to look for at a random basis to look for specific functions. Again, we encourage really thoughtful analysis of the source of the genes, whether it may be more important the source than whether the function is known or unknown, especially at very small-scale testing that is required to do some of the screening and selection and identification of function.

MR. SCHNEIDER: One of the comments you heard the other day when we were talking about the expedited reviews for imports, I am curious as to how you are coordinating with the FDA on food issues and certainly with the EPA with its trip related as you look at imports that are intended for food or feed use, or are you?

MR. TURNER: At this time, we are not. If it has undergone review at APHID. of course, you would have to have to bring it in. I am probably missing

the point.

MR. SCHNEIDER: Well, I am looking at some imports here.

MS. SMITH: You are talking about the notice in terms of the direction that we are thinking about moving in.

MR. SCHNEIDER: Right.

MS. SMITH: Incumbent upon considering looking at whether something should be exempt, we would have to be working closely with the EPA in terms of that approach. It would either be in situations where we are working closely with them, or if they provided the review. It was something that just didn't come to us for review because it was not intended for propagation.

MR. SCHNEIDER: Okay. And it would obviously have to had some prior approval in the exporting country?

MS. SMITH: That is correct.

MR. SCHNEIDER: Okay.

MS. SMITH: So the kind of comment we wold appreciate is: How do you approach, for example, considering the process in the country of origin? And should different countries be looked at differently?

MR. FUCHS: Again one thing that we would

apply to the USDA and your sister agencies is the harmonization and outreach to other countries because surely on a topic like imported products becomes very critical. as Cindy had indicated about the regulatory process in the country of origin.

Given as I take it as you look at your policy on imported products, or commodity products, as you develop your policy, you will also be looking at working with other countries around the world on how they would recognize similar questions from products that are produced in the U.S., and exported to other countries, so that there would be some mutual understanding or harmonization around how exports are handled in the U.S. from other countries, and U.S. exports to recipient countries.

MS. SMITH: Yes, that is a very good point. One of the things that you are probably aware of that we have done with the creation of BRS is establish a separate regulatory capacity to go with a function with the sole intention of helping other countries develop like science-based systems. So I think that is really going in that direction and that is a good comment.

MR. SCHNEIDER: And that is where Dave is fitting into a part of this program as well, I guess,

is working to help do that or not?

MS. SMITH: Actually, yes, he is. He is not specifically in that staff structurally, but yes that is exactly one of the most important contributions that we are making right now, regulatory capital capacity building is the work that Dave is doing.

MR. SCHNEIDER: Good.

MR. DOBERT: We have a couple of questions about Question No. 3, the regulatory flexibility that has been outlined. I imagine that some of the comments that were heard earlier in the week that that is a topic of great discussion.

One of the things that we just wanted to articulate in sort of applauding the system on the job that they have done in the past and recognizing that there is already considerable flexibility that we feel that you have in terms of allowing commercialization underneath what will continue regulatory oversight essentially because there is the ability. The Agency can now grant a petition in whole or in part. So we would acknowledge that there is that flexibility right now built to the system.

But what additional flexibility beyond, in whole or in part, do you really foresee wanting to address in any revised rule?

MS. SMITH: A couple of examples -- and again, we are trying to kind of look down the road and build in flexibility that will really position us well for the future: evaluation of products. A couple of examples: one would be the situation in which we wanted to consider issuing an approval with some conditions. So, while we wouldn't feel that we could reach a decision that would allow us to approve something for a full unconfined release, there may be an approval we could issue with some additional restrictions, such as where it might be used. That might be one example.

Another example of the flexibility that we are looking at there is having the ability when there is a minor unresolved level of risk associated with an approval, something that is a level of risk that is not significant enough to stop the approval, yet we think that a full approval would benefit from having some additional information. Perhaps that additional information will only be able to be gathered by allowing the approval.

One of the things that we are talking about is maybe an approval with the need for gathering a certain amount of information over a limited period of time. That could be information we might gather, the

company might gather, or we might have a scientific society gather that information. And then that information can be factored into a reconsideration of that for a full approval at some later time. So just a couple of hypothetical --

MR. DOBERT: Would you foresee reaching any different end point in making that assessment because, again right how, the end point that is reached is that it does not pose a significant plant test risk in that there is a finding of no-significant impact to the environment.

If something was -- that you did have some conditions imposed, would you still want to be reaching those same findings?

MS. SMITH: Would we want to reach those same findings, or would that be the objective?

MR. DOBERT: Would that be the objective of the --

MS. SMITH: When you issue the first or the second?

MR. DOBERT: When you issue the first, would you be issuing some kind of an approval with conditions but what kind of a conclusion would you be able to reach with regard to plant-test risk and impact on the environment?

MS. SMITH: That is a good question. I don't know, John, if you have a --

MR. TURNER: Certainly, if the restriction required monitoring, that monitoring would have to be tied to a risk. We wouldn't reach the conclusion that it is as safe as any other crops, as you have to monitor it and you don't have to monitor other crops. Then that would be inconsistent and so we are looking at special case situations where there would be minor unresolved risk and it looks like that might leave open the possibility that the end point would be different in the initial evaluation.

MR. FUCHS: Maybe one more clarification. One of the things that we were thinking about in terms of my company that would have a product that perhaps had a condition or registration. Two concerns really are probably foremost in our minds. One is: Does the kind of information that is raised and the decision that would be made based on that information, I guess our assumptions would be that they are minor or unresolved risks, that those risks, hopefully, are more risks that could be addressed through management practices verses risks that would have any bearing on whether the product had continued to be used in the environment.

Again, once you had a commercial release that becomes extremely important from the company's perspective as well as the other aspect. And I think that you can probably address both of these at the same time: Is the impacts that would have for countries that looked to USDA process in making their own risk assessments.

If you could address both of those, particularly the first one: Whether you see any of the unresolved risk and whether the data would in any way -- I think where Ray was coming back impacted the decision of the ability to continue those products in the marketplace; or whether more how they would be used and things that could be managed versus removed?

MR. TURNER: We have had several questions around on how you would define a low level of risk and, of course, it is a great question and I am not sure that IA have a great answer. But we would anticipate certainly have full anticipation that there wouldn't be a change of decision. That it is going to be allowed full commercialization, or we would never let it go forward. If there were major risks, we wouldn't want it to go forward.

So we were talking more about the type of litigation or data that could be gathered over time.

But to allow us to have continued oversight during that time period. Again, the types of crops that have come through to date are not necessarily what we are thinking about. This is very forward looking.

MS. SMITH: The majority of what is in the system now would not need this flexibility. We are not really facing products today that we are thinking we need this flexibility for. It is more positioning the system to be able to deal with what is going to be coming down the road and just trying to build in as much flexibility as we can.

But we do certainly appreciate any comments that you have for us to keep in mind as we look at building that flexibility.

MR. SCHNEIDER: One of the watch outs to see if -- and Robin can probably assess to this: When you start putting conditions on it essentially drives you towards a review that will be mandated within a given period of time as well.

One of the problems that you get into then is that overlap of timing when one expires and the other has to go into effect not to impact all these things down stream. So as you develop this concept keep that in mind about the amount of time and resources necessary to evaluate the new data that you

are asking for without impacting all these other changes, if you change from conditional to a full approval.

MR. DOBERT: Again, along that line, and Lorraine touched on it, is that: A lot of times, your international counterparts will, if they know that a decision is upcoming on a particular product where essentially something has to be renewed or conditions may be lifted or continued, they will defer on making their decisions until that time has come and gone and the Agency has made a decision; and that has potential impacts on international trade.

MS. SMITH: Good point.

MR. DOBERT: One of the areas that has recently been adopted on petitions that have been completed and approved is the requirement to report information that differs substantially from that which was described in the petition, or might be considered to be maybe adverse-affects reporting.

We would consider that that kind of data request would enable APHIS to continue to provide some regulatory oversight even though these products have, in fact, been "deregulated." So in terms of the notion of saying that there are no regulatory restrictions which remain on the product which have

been deregulated, I think is a fallacy that many people -- I think the Agency should take credit for the fact that they do have a continuing role to play and if there was significant information that came into the Agency, you could take action -- because something is deregulated it can be reregulated as well.

MS. SMITH: Thank you for that point. One of the things that has become very clear to us is the need, in our new regulations, to make it more explicit that we do have this authority even today and there is probably something more that we need to do now to make this more clear.

It has been surprising how many organizations and individuals are unaware that we do have that ability.

MR. DOBERT: So given that ability, and I know that your questions don't specifically lead one to make the conclusion that the deregulation process is something that you would be moving away from. Can you comment on what deregulation -- and again, I think that is statutorily built into the law but would you continue to have a deregulation option for those products, which again there is a certain degree of familiarity and experience with?

MS. SMITH: We would still have a deregulation mechanism within the system. It has worked very well. What we are talking about doing is just adding some enhancements to that system.

So, as we add those enhancements into this kind of flexibility, we may change the name. We may move towards terminology that is more internationally accepted, such as approvals. But, essentially, the heart about what we will be talking about will be our deregulation system just with some added bells and whistles essentially.

MR. DOBERT: One other question going back to -- if there were conditions posed to help resolve minor unresolved risks, I think that John might have touched on this already but just to get further clarity: Do you think that there would be a benefit in laying out specific time frames or even maximum time frames during which that kind of data or those kinds of restrictions would be placed on the product, so that again it sort of gives everyone advance notice that these aren't going to be something that remain on the product forever, or essentially the issue is either going to be resolved or answered in some way?

MR. TURNER: That is a good comment and that is certainly something that we recognize here at the

regulatory center.

MS. SMITH: And would welcome specific suggestions along those lines in the conference.

MS. SCHUETTE: So maybe just to follow-up on that a little bit before I get to my more general questions. It seems like this minor unresolved risk category is hard for me to understand exactly how it differs from no significant risk in how a risk assessment might be conducted. So what it really seems in some ways to do is to create a grey middle area. so I guess I would be wondering: How you would make a definition between a finding of no significant risk versus a minor-unresolved risk and whether or not there is a tendency for that to maybe overlap at all?

MS. SMITH: That is a good comment. How we define minor-unresolved risks is a key element of what we invite comments on.

MS. SCHUETTE: I have maybe more just some general-process questions focused on -- I am kind of moving forward actually in the interim mentioning that we have several products that are currently deregulated and on the market. So, of course, we are interested in whether or not you anticipate any changes in the status with regard to currently deregulated products and what would happen with those?

MS. SMITH: All products that have already come through the system would be grandfathered in. So what we are talking about is strengthening deregulation, not validating it in any way.

Certainly, things that have already come through that system would still be deregulated or accrued. Then what we would be meaning to do is looking at what is in the system as we got close to issuing our final rules, we would look at how those would be affected and we would be communicating with stakeholders so that you understood.

MS. SCHUETTE: I suppose --

MR. DOBERT: There is, I would think a legal distinction, though, between something that is deregulated and something which is not, something that is approved. So I think one of the questions is: What would the status of the current products on the market would be?

Would they continue to be considered deregulated and essentially not subject to the regulations or would be in this -- again, there is a legal line that one can draw either between our subject and to the regulations, or not; and which way would those products tend to fall, the products currently on the market?

MS. SMITH: We can certainly look at that. I don't think that we have seen any reason to think that they would be resubjected, that they have already cleared the regulatory system.

MS. SCHUETTE: So maybe it would be another category that isn't available any more, but would still be there or something?

I think you may have alluded to this. It doesn't get closer, the things that are about ready to come out of the review process but, of course, we also talked about the fact that we are expecting revisions to Part 340 to probably take a couple of years. So we very interested in knowing what is going to happen to products that are either currently in the review process, or products that would be submitted in the normal course of time between now and when the new regulations would actually be finalized?

MS. SMITH: I think the best thing that we can do for our applicants is to just keep them well apprised of where we are in the process, so that they have a sense of the time line to when they can expect the new regulations to go to place and how that will impact what is coming into the system.

We have a plan for our time line for when we will finalize our rule, but there is an awful lot of

work to be done, so that is a plan. So the best thing that we can do is just make sure that we are keeping everyone apprised of the status as we try to build in some kind of a transition plan.

MS. SCHUETTE: So you will make regulatory decisions between now and when the rule is finalized?

MS. SMITH: Absolutely.

MS. SCHUETTE: Okay. I didn't know if there was a --

MS. SMITH: We are not going to stop working.

MS. SCHUETTE: Obviously, that is something that --

MS. SMITH: Although that would be one way to expedite what we're doing, but we haven't sorted that out yet.

(Laughter)

MR. DOBERT: Or there would be another way to expedite it.

MS. SMITH: That would be to essentially get all the interesting products that have been submitted off the docket.

Okay. We appreciate your comments.

MS. SCHUETTE: Of course, as you go forward, one thing that we really didn't see in the questions

or in the Register notice was: Whether or not the Agency intends to make any changes in the petitions under the noxious standard under the PTA or anything there?

MS. SMITH: I think it is likely that if we move to expand an authority where we are, leveraging let's say for example, the noxious weed authority, you can look at the definition of a noxious weed to give you a sense of how our review of products coming in will be broadening.

Now, some of the things that are covered under that, such as food safety, are addressed by our sister agencies within the coordinated framework. So that does not necessarily mean that we doing that work, but it is likely that we will be factoring the roles that our sister agencies play in our looking at it, the environmental effects and food-safety effects.

MS. SCHUETTE: One of the things that we talked about were these different categories of commercialization or approval of deregulation or whenever we get to, as part of that, we were wondering whether or not the Agency is considering that the recipient of whatever that commercialization approval is would be accorded data-protection rights?

MS. SMITH: I am sorry. Can you repeat the question?

MS. SCHUETTE: What is the more positive approval process that you are talking about with regard to commercialization. We were wondering or not you considered building in data protection or data-compensation capabilities to that as well?

MS. SMITH: Actually, that is an issue that has just recently been raised. I think that is one where we are open to receiving comments on, as any of these areas.

MS. SCHUETTE: Okay.

MR. TURNER: I remember that the vast majority of the products will be moving through and reaching an end point which is synonymous with deregulation, as we know it to date for administration of our license --

MS. SCHUETTE: But when you say that it is synonymous with deregulation, I guess the question is: Will that approval be a general approval, or will the approval be associated with a particular applicant?

MR. DOBERT: In other words, is it an approval which is granted to the product independent of the fact of who developed it, or is it actually --

MS. SCHUETTE: Or who provided the data?

MR. DOBERT: Or who provided the data, right. Or, in fact, to a specific applicant who has prepared that data and is specifically requesting a specific approval or decision from the Agency. Again, if you look at the EPA as an example, you get a specific registrant who holds the registration.

MR. TURNER: Under our current system of deregulation, the deregulator is the deregulator.

MS. SCHUETTE: Right.

MR. TURNER: Is it not?

MS. SCHUETTE: Yes. So that is the question then. You said that you still have that category, then we are assuming that it stays the same. If you don't have that category and it is an "approval" or registration, then how will that be treated; and would it be treated any differently?

MR. TURNER: I would say, again, even if the choices are if there are some conditions which were placed upon that --

MR. DOBERT: Yes, the conditions are sort of provided to the applicant sitting there rather than to the product in general. Would that be your assumption as well, that there is a definite tie in that you are telling an applicant that these are the conditions?

MR. TURNER: Yes.

MR. WHITE: I'm Jim White at APHIS Regulatory Biologic. Their license is granted to the applicant and the product, just like EPA. They are linked.

MR. DOBERT: Just one question: Do they also do the same thing for biological control organisms right now?

MR. WHITE: No process.

MR. FUCHS: The other part to that, which we are very supportive of transparency and make a lot of the information on our products available. But as we continue to be more transparent and more of the information becomes available, I think this question becomes even more so. The group that actually developed the data and having some rights to that information to insure that it is not of general use for everyone for other competing products becomes very important because there is a large investment to develop that information.

So were thinking of helping in the process of moving to a more formal approval process, that some of the conditions, as we have commented, that EPA uses would be applicable to how to provide some protection on it, the data that would be very broadly available.

MS. SMITH: We can certainly consider it.

MR. TURNER: Some of the --

MS. SMITH: Right.

MR. DOBERT: So I know that currently for a number of the processes, be it for notifications or permits or for deregulation or decisions, the determinations of non-regulated status, each of those has specific time lines which are built into them.

We do foresee building in specific time lines into any future system that is to be developed. Again, I think it would be consistent with most regulatory systems within the OECD do set some kind of time frames for which reviews should take place.

MR. TURNER: We recognize the value of time lines and we are looking at that to see if the present time lines are adequate and what should be the appropriate time lines?

MS. SCHUETTE: So I don't think that we are asking you to commit to any specific time lines here, but I guess we are advocating that they should be built into the statutory guide-line process.

MS. SMITH: Okay.

MS. SCHUETTE: Maybe then, maybe we should actually move down to some of the other areas before we come back to what we had originally listed as kind of our two questions because we have more time than we

originally thought that we might.

We have gotten through some of these rather speedily. Ray, maybe you --

MR. DOBERT: Sure. So some of these things are more process oriented to the -- or the overall EIS is process as well as its scoping process. Will the Agency, I know you certainly alluded to it in the *Federal Register* notice, but will the Agency continue to ride on the existing definition of genetically engineered organisms? And will that essentially be the scope of the EIS that will be conducted?

MS. SMITH: That is one of the things that we are looking at. I think, at this point, we don't have any reason to believe that it would change, but maybe I should defer to John, if you could work off this discussion.

MR. TURNER: I think that was a good answer. We are looking at whether we want to stay with this for awhile. With this system, using genetically engineered, or do we want to go to a pure trait-based system, or what parts could be processed? More than likely, as you said, stay with something that was smaller.

MR. DOBERT: And that would probably one of the first key things, because in terms of defining the

overall scope of the EIS is there a step-wise process because -- you have to answer that question, I assume before you can move to some of the other questions.

MR. TURNER: Yes. We are working on that specific issue.

MR. FUCHS: One other question relative to scope, you mentioned in the *Federal Register* notice about the scope often including genetically engineered microbes and arthropods. Will your EIS be that broad? Will it be more plant focused. Can you give us any broad -- be that the scope of organisms?

MR. TURNER: It will have to be that broad inasmuch as we have the regulatory changes that affect those things. So it will be kept broad.

MR. FUCHS: Okay.

MR. DOBERT: I would assume that as part of the EIS process, that a component of that will be the Economic Impact Assessment. Is that correct?

MR. TURNER: Yes.

MR. DOBERT: Do you have -- I don't want to throw around the process but do you have any idea, can you comment on the key factors that you would use in that assessment? And where the particular focus will be? When you are looking at cost, will it largely be focused on the cost of complying with the regulations

themselves, and not particularly on the products themselves but on the costs and then put up the process?

MS. SMITH: That is a good question that we would be in a better position to answer -- I mentioned earlier the key Agency personnel that will be supporting the process will be sitting in on some meetings. We have had sitting in on some of the meetings the Staff that is contributing the economic elements, which is another part of APHIS. But she is not in this session, so I think that we really much of a sense of what is going to be tracking into that economic analysis at this point.

MR. DOBERT: I guess one time it would be that we would smuggest that the economic assessment should be focused on costs and benefits associated with the process that would be --

MR. WACH: Which process, I'm sorry?

MS. SMITH: The regulatory.

MR. DOBERT: The regulatory process in terms of like of: How long the paperwork requirements? How much it takes for data generation? What are the times it would take the Agency for analyzing the information? Again, because it is a problematic EIS that is not focused on specific products, I think that

it should be targeted towards the process of what you do in permitting and regulating by a product.

MS. SCHUETTE: Roy, do you want to want to make another imports, or where are we now?

MS. KOEHLER: Can I clarify? So you are suggesting that it not include an analysis of industry costs?

MR. DOBERT: No, no, that it should.

MS. KOEHLER: That it should include them.

MS. SCHUETTE: The costs associated with the regulatory process itself that is what we believe the focus should be.

MR. DOBERT: Right. The costs and benefits associated. So, again, the costs would be for collecting the data, compiling the data, submitting the data.

MS. SCHUETTE: And reviewing.

MR. DOBERT: And reviewing the data. Those kinds of costs. So, again, I guess the benefits would be: What does APHIS get out of it? What does the public, at large, get out of having an enhanced system?

MR. FUCHS: So maybe our last couple of questions related; and we have talked a little about the imports. But being that we are all aware that the

COPMOP meetings are ongoing as we speak, it becomes very important on the international front that any other information relative to environmental assessments of imported products, which is referred to as the LMOFFPs that have no intention of being released into the environment.

We have touched on it earlier but I was curious if you have had any more insights for things that have no intent for release, so it is a commodity product entering the U.S. really as a commodity? Does USDA have recommendations or anything that you could provide to us relative to how you would see if there is necessary environmental assessment for those, or how you would handle those products, and whether it is differentiated by the product, etc., or their use?

MR. TURNER: Well, we were looking to just see if we could address, through the EIS, the categories of products and things that you might qualify. So you can think in terms both of the types of crops and of the types of traits and are there risk assessments that can be done on those classes?

Beyond that, I don't think that there is a lot that we can say specifically at this time. And then there is the issue of whether it is a static group, or whether they can be added to over time when

we recognize the importance of flexibility?

MR. DOBERT: So, John, to follow up on that because one of the things that you can obviously do is you can set specific eligibility criteria, and then it is more driven by the applicant to sort of walk through that and say: Do I or do I not meet certain eligibility criteria versus an applicant just submitting whatever they have to APHIS and APHIS de novo kind of making an assessment of all of the information.

In terms of one process over the other of establishing up front eligibility criteria versus saying: We are going to make the assessment on every single product and we don't have all the eligibility criteria. We just say that it is going to wind up in one of several buckets. If you had to say a direction that you would be leaning towards right now, which one?

MR. TURNER: It is an evolving process. So we don't know which one. But most of our discussions have been along the lines of the first one where the eligibility criteria and those are the types of things that can be addressed in a risk assessment.

MS. SCHUETTE: I think that one of the things right now that we are seeing as the leaders --

MR. TURNER: Excuse me.

MS. SCHUETTE: Go ahead.

MR. TURNER: I said that we would love to hear input on that as to what you think is the most appropriate. That is the stage we're at. We are very early in the process; and we wanted to have stakeholder sessions very early.

MR. DOBERT: Both on the process as well as if there are specific eligibility criteria that we think should be incorporated or --

MR. TURNER: Both would be of interest. It would be an overall approach and the criteria.

MS. SMITH: As you are looking at the questions here, please give yourselves great latitude in terms of what kind of information that you give us in your comments.

We really are very much at the early stage of this and have a general idea of how we are going to approach revisions. But there is a lot of work still to be done and we are very open to input.

MS. SCHUETTE: One question that really has us all stumped is the question of non-viable material. So I don't know if anyone here could perhaps elucidate what may be the intent was on that, so that we can provide a simple answer?

MS. SMITH: Well, actually, that is a lot simpler than it looks. If you look at the definition of a noxious weed, if we move to that authority, a distinction between the Plant Pest Authority and the Noxious Weed Authority is that with Plant Pest Authority, we are limiting only at looking at plants, or viable plants, parts of plant.

In the Noxious Weed Authority, it is a different definition in terms of how they define noxious weeds. So it is plants or plant products. So we don't have something specific in mind, saying: We want to regulate the end product. It is just more an acknowledgement to the public that the definition is different. So we could have more latitude there if we choose to exercise it.

So we would see comments about the availability of that, the distinction of that kind of language and what the implications would be if we were to consider or not consider leveraging that aspect of that authority.

MR. DOBERT: Just a follow-up on that is that I would imagine that -- again, if there is tier reviews, there would be some products where non-viable material would be potentially at issue or a concern; and other products where it would potentially not be.

MS. SMITH: That's a possibility.

MS. SCHUETTE: I'll ask this since we have it in our list of questions. But I think that I know the answer based on some of the previous comments but we are interested obviously in the next steps and also if there is any information on time frames with regard to: When the EIS will be prepared and when the final regulations took place?

MS. SMITH: I can tell you that our best guess, at this point, is: Our objective is to complete the draft of the EIS this year.

We recognize, at the same time, that that is an incredibly optimistic and ambitious goal, particularly with the workload that we have. But I would say that it is a priority for the Agency and we are receiving a lot of support in order for us to meet that goal.

Then our intention with the EIS is that would inform the rule-making process, so a lot of the discussion and analysis that will go into the EIS is also the same kind of discussion and analysis that we need to have for the rule making. Our intention would be to have our proposed rule issued some number of months after the draft EIS comes out.

What we said is that we don't anticipate

this rule affecting this or the next growing season. But we are hoping that within a couple of years, we will be able to complete our final rule. Again, that will be determined by the scope of comments that we receive each step of the way.

MR. DOBERT: Once the public time period has closed, what specific steps is APHIS going to do then to move the process forward, both in terms of providing feedback to stakeholders on: What is happening; what is the Agency's response to the comments; what is the scope of the EIS; what opportunities will be there for the stakeholders to sort of know what is going on and where progress is being made?

MS. SMITH: Prior to the issuing of the draft EIS you mean?

MR. DOBERT: Yes.

MS. SMITH: I am not sure, at this point, what else we will be doing during that process. We talked, for example, about -- this is an area where I think it really involves every day working on the EIS.

One of the things that we talked about is whether we want to consider helping us to find and address some of the specific issues? Whether we want

to convene in subgroups and get some outside input on some of those issues, for example, that would help us with the analysis?

We don't have anything very firm at this point in terms of specific steps that will be due in between the posting of the comment period and the issuing of the EIS. But, again, we are open to any kind of suggestions. That is certainly something that you can include in your comments if there are specific steps that you think could enhance our transparency that could be answered under the final call in the notice about any other comments that you would want to provide us. You can entertain those and you can provide them under that.

MR. FUCHS: So the one thing because the request for input specifically it is asking to help delineate the scope of issues and alternatives, again, it seems like a long time between when you get input from the public and when you issue a draft EIS. Would you publicly delineating what you consider to be the scope of the EIS?

MS. SMITH: I would imagine that we would but I am not sure exactly what the kind of a process would be for that.

MR. FUCHS: Okay.

MR. SCHNEIDER: One thing that I think I know we have discussed, but continues to be something that we are concerned about: As yo go through the process and nightmare, it is truly an opportunity, as you commented on, about expanding or modifying the data requirements. You know that it is clear that it probably takes two or three years from knowing what the data requirements are to develop new data, to be able to get the data analyzed and submit it, have it reviewed.

And this transition time that we have talked about, again, we would just encourage as you look at transition times, that you really look at the length of time. Because a lot of times people don't appreciate the time lag to understand the requirement. As Sheila commented, when we know that relates to field seasons, how many field seasons? Some of these can be two to three to four years from knowing what a requirement is to being able to have data that you can review in terms of making decisions.

So we encourage you to take that into account and perhaps how you do the transition would be very important.

MS. SMITH: Very good comment, thank you.

MR. SCHNEIDER: One of the comments made

earlier was that we were going to make comments available somewhere. Do you have any idea on timing once you are finished?

MS. SMITH: It will be sometime after two weeks from now. I am not sure if it will be prior to the public-comment period closing. Ideally, I think we might have it before that, but we have to see what our time frame is in terms of our product delivery from the transcriber.

MS. INGEBRITSEN: How will this be made available, the transcript?

MS. SMITH: The transcript, we are considering posting this on our Web page and it will also be included as part of the public record.

MR. SCHNEIDER: So it will be in the docket?

MR. FUCHS: Again, we really appreciate the clarity and the responses today and look forward to -- and I think it really will help us in terms of crafting our own responses and appreciating the clarity and opportunities for providing comments.

We really appreciate it. I don't know if you have any questions you would like to ask. We have been on the questioning side for the last hour but I think that we have gotten the level of clarity that we need to go back and finalize your comments. So we

really appreciate this opportunity and the openness in responding to a long list of questions that we brought to you today.

MS. SMITH: Thank you. We don't always have as clear answers as we would like to give. But, again, we really are at the beginning of the process and we really looking for input into what we need to consider.

If you could, we would like to take a couple of minutes to see if we do have some questions that we would like to ask you as well.

Any questions?

MS. ROSE: Robyn Rose from BRS. I would like to ask just Monsanto's opinion on some environmentally ecological effects monitoring in where you would see APHIS's role in that? For instance, monitoring for a non-target population effects or insect resistance?

MR. SCHNEIDER: Coming out of EPA, that was really a loaded question.

(Laughter)

MS. ROSE: That is why I asked the question: Where do you see APHIS's role in a monitoring context as opposed to EPA's role?

MS. SCHUETTE: Well, for purposes, I guess I would say that we believe that EPA has the appropriate

authority under the coordinated framework to take the lead in that area, although all the agencies, of course, that are on it.

MR. FUCHS: I think probably the other -- again, we weren't really prepared for that specific question, but we would assume that those would be part of the pre-market assessment process as you go through it that these would be exactly the questions you would be asking; and whether there would be any unanswered questions that would require monitoring, you would really again have to be very risk based and I assume that that is part of your consideration for looking for potential approvals with conditions.

But we would hope that the vast majority of any of those questions would be asked, raised and resolved as part of the pre-approval process and built to appropriate regulations, so that they can be addressed prior to rather than following the commercial approval.

The question that we always -- and, again, we ask this question not only in the U.S. but, of course, in Europe and around the world is: What are the risks that may not be fully resolved prior to and may require monitoring? We have identified very few of those that we h ave seen that monitoring seemingly

adds value that can't be addressed in a pre-market process. So we would strongly encourage you to have as much thoughtful discussion to have those included in the regulations versus post-market monitoring processes.

I hope that totally answers your question because it really get down --

MS. ROSE: I guess I was thinking more in the post-commercialization monitoring to make sure that resistance or some sort of an adverse effect did not occur.

MR. FUCHS: And I think the other question that we need to take into consideration is: One of those really are an adverse effect from an environmental-risk perspective versus a commercial risk perspective. Of course, we are accountable to assure that our products have longevity and not every product will have an unlimited effectiveness.

So I think you would really need to consider which of those are commercial products for farmers versus really adverse risk assessment that would need to be done in the risk-assessment process itself.

MS. SMITH: Okay. Do you have any other questions? Okay. Thank you.

We really appreciate your time. This has

been constructive for us. The more questions you have, of course, relates to have prior thinking even more fully than we have already have kind of started. So we look forward to factoring in your thinking and I am sure this will be a process in which there will be a lot of opportunities to continue to interact with you.

So thanks again for your time.

UNISON: Thank you.

(Whereupon, at 1:13 p.m., the meeting in the above-entitled matter was concluded.)

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REPORTER'S CERTIFICATE

CASE TITLE: STAKEHOLDERS MEETING WITH MONSANTO

HEARING DATE: February 27, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 27, 2004

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